## REMARKS

Claims 1-6, 8 and 11-14 are currently pending. Claims 3 and 8 are cancelled. Claims 1 and 5 have been amended to further clarify the scope of protection to which the applicant is entitled. Support for the amended claim recitations is found throughout the specifications and the original claims. See, for example, original claims 3, 8.

No new matter is added.

I. Claim Objections

Claim 8 stands rejected as allegedly indefinite because the term "50 x $10^6$ per ml" appears to lack the word "cells". This rejection is respectfully traversed.

As noted above, Claim 8 has been cancelled. As amended, Claim 1 and 5 clarify that the MSCs of the pharmaceutical compositions of the present invention are present in a concentration of about 50 x $10^6$ cells per ml of polymer. It is respectfully submitted that this objection be withdrawn, since the claims, as amended, render this objection moot.

II. Claim Rejections under 35 U.S.C. § 112

Claims 1-6, 8 and 11-14 are rejected under 35 U.S.C. 112, first paragraph, for lack of enablement. The rejection is respectfully traversed.

As noted above, claims 1 and 5 have been amended. It is respectfully submitted that the claims, as amended, overcome this rejection and withdrawal of this rejection is therefore respectfully requested.

III. Claim Rejections under 35 U.S.C. § 102

Claims 1-2, 11 and 13 remain rejected under 35 U.S.C. 102(b) as allegedly being anticipated by Moutsatsos et al. (WO 99/11664) Claims 1-2, 4, 11 and 13 remain rejected under 35 U.S.C. 102(b) as being anticipated by Riew et al. (Calcif. Tissue Int. 63:357-360, 1998) as evidenced by Caplan et al.(U.S. Patent No. 5,885,619). Claims 1-2, 4, 11 and 13 remain rejected

under 35 U.S.C. 102(a) as allegedly being anticipating by Cheng et al.(Calcif. Tissue Int. 68:8794, 2001) as evidenced by Caplan et al. These rejections are respectfully traversed. As amended, the claims recite that the MSCs of the pharmaceutical compositions of the present invention are present in a concentration of about 50 x 10 to the sixth cells per ml of polymer. None of Moutsatsos el al., Riew et al. Cheng el al. or Caplan et al. teach or suggest a pharmaceutical composition for application at a biodegradable plate-containing site requiring new bone formation in a subject, comprising a plurality of bone marrow stromal cells (MSCs) and a pharmaceutically acceptable polymer, wherein the MSCs are isolated from the subject; are transduced *in vitro* after isolation from the subject with a replication-deficient viral vector comprising a DNA sequence encoding BMP-2 operably linked to a promoter, and are applied at the biodegradable plate containing site in a concentration of about 50 x $10^6$ cells per ml of polymer. References without this teaching fail to achieve the results of the current invention.

As such, Applicant respectfully submits that the claims are not anticipated by any of Moutsatsos et al., Riew et al. or Cheng et al., and withdrawal of this rejection is respectfully requested.

IV. Claims rejected under 35 U.S.C. § 103

Claims 5-6 and 12 are rejected under 35 U.S.C. § 103(s) as allegedly being unpatentable over Moutsatsos et al. in view of Kadilaya et al. (U.S. Patent No. 6,541,024). This rejection is respectfully traversed.

As amended, the claims recite that the MSCs of the compositions of the pharmaceutical compositions of the present invention are present in a concentration of 5 x 10 to the sixth cells per ml of polymer. Moutsatsos et al. do not teach or suggest a pharmaceutical composition for application at a biodegradable plate-containing site requiring new bone formation in a subject,

comprising a plurality of bone marrow stromal cells (MSCs) and a pharmaceutically acceptable polymer, wherein the MSCs are isolated from the subject; are transduced *in vitro* after isolation from the subject with a replication-deficient viral vector comprising a DNA sequence encoding BMP-2 operably linked to a promoter, and are applied at the biodegradable plate containing site in a concentration of about 50 x $10^6$ cells per ml of polymer. Kadilaya et al. do not overcome the deficiencies in Moutsatsos et al.

As such, it is respectfully submitted that claims are not unpatentable over Moutsatsos et al. in view of Kadilaya et al. and withdrawal of this rejection is respectfully requested

V. Claims rejected under 35 U.S.C. § 103

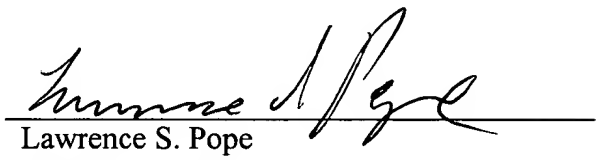
Claim 14 is rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Moutsatsos et al. in view of Kadilaya et al. as applied to claims 5-6 and 12, and further in view of Tschakaloff (U.S. Patent No. 5,290,281). This rejection is respectfully traversed.

As noted above, claims 1 and 5 have been amended to further clarify the scope of the present invention. Moutsatsos et al. do not teach or suggest a pharmaceutical composition for application at a biodegradable plate-containing site requiring new bone formation in a subject, comprising a plurality of bone marrow stromal cells (MSCs) and a pharmaceutically acceptable polymer, wherein the MSCs are isolated from the subject; are transduced *in vitro* after isolation from the subject with a replication-deficient viral vector comprising a DNA sequence encoding BMP-2 operably linked to a promoter, and are applied at the biodegradable plate containing site in a concentration of about 50 x $10^6$ cells per ml of polymer. Neither Kadilaya et al. nor Tshakaloff et al., alone or in combination, remedy the deficiencies in Moutsatsos et al.

As such, it is respectfully submitted that claims are not unpatentable over Moutsatsos et al. in view of Kadilaya et al. and further in view of Tshakaloff et al., and withdrawal of this rejection is respectfully requested.

In view of the above, it is respectfully submitted that the claims are in condition for allowance. The Examiner is encouraged to contact the undersigned with any questions or to otherwise expedite prosecution.

Respectfully submitted,



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